UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,049	05/05/2008	Jeffrey W. Strovel	689290-275	4653

27162 7590 06/15/2010

CARELLA, BYRNE, CECCHI, OLSTEIN, BRODY & AGNELLO
5 BECKER FARM ROAD
ROSELAND, NJ 07068

EXAMINER	
MYERS, CARLA J	
ART UNIT	PAPER NUMBER
1634	
MAIL DATE	DELIVERY MODE
06/15/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/591,049	STROVEL ET AL.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-60* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-4, drawn to methods for identifying an anti-neoplastic agent comprising determining a change in an amplification ratio of an amplicon from Table 2.

Group II, claims 5-9 (in part), drawn to methods for identifying an anti-neoplastic agent comprising detecting a change in the level of a nucleic acid selected from SEQ ID NO: 1-3049.

Group III, claims 5-9 (in part), drawn to methods for identifying an anti-neoplastic agent comprising detecting a change in the level of a polypeptide encoded by a nucleic acid selected from SEQ ID NO: 1-3049.

Group IV, claims 10, 11, 48-55, and 57-60 (in part), drawn to methods for detecting a cancerous status of a cell and methods for determining the likelihood of success of cancer therapy comprising detecting an increase in the level of a nucleic acid selected from SEQ ID NO: 1-3049.

Group V, claims 10, 11, 48-55, 57-60 (in part), drawn to methods for detecting a cancerous status of a cell and methods for determining the likelihood of success of cancer therapy by assaying for the level of a protein of a protein encoded by one of SEQ ID NO: 1-3049.

Group VI, claims 12-39, drawn to methods for identifying an anti-neoplastic agent comprising determining a change in the biological activity of a polypeptide encoded by a nucleic acid selected from SEQ ID NO: 1-3049.

Group VII, claims 40-44 (in part), drawn to methods for treating cancer with an agent identified using the method of claim 1.

Group VIII, claims 40-44 (in part), drawn to methods for treating cancer with an agent identified using the method of claim 5, wherein the method of claim 5 detects the level a nucleic acid.

Group IX, claims 40-44 (in part), drawn to methods for treating cancer with an agent identified using the method of claim 5, wherein the method of claim 5 detects the level a polypeptide.

Group X, claims 40-44 (in part), drawn to methods for treating cancer with an agent identified using the method of claim 12.

Group XI, claim 45 (in part), drawn to methods for treating cancer with an agent that binds to a nucleic acid selected from SEQ ID NO: 1-3049.

Group XII, claim 45-47 (in part), drawn to methods for treating cancer with an agent that binds to the a polypeptide encoded by one of SEQ ID NO: 1-3049.

Group XIII, claim 56, drawn to a method of producing test data comprising identifying a test compound according to claim 12 and producing test data to determine the chemical structure of the test compound.

2. The inventions listed as Groups I-XIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

A 371 case is considered to have unity of invention only when there is a technical relationship among those inventions involving one or more of the same or corresponding technical features. The expression “special technical feature” means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. In the instant application, the technical feature of invention I – i.e., methods for identifying agents having anti-neoplastic activity by assaying for a change in the level of amplification or copy number or expression of a nucleic acid - was known in the art at the time the invention was made. For example, Smith et al (US Patent No. 5,776,683; cited in the IDS; col. 6 and 25) discloses a method of identifying anti-neoplastic agents wherein the method comprises: a)

contacting a cell containing a gene sequence that is amplified and has an amplification ratio of at least 2; b) detecting a change in the amplification of the gene following exposure to the test agent; and identifying a test agent as being an anti-neoplastic agent if there is a change in amplification as a result of treatment with the test agent. Smith teaches that a change in the amplification of the gene can be monitored by assaying for a decrease in expression or by assaying for a change in copy number (see col. 25). Moreover, while Smith does not specifically exemplify methods in which the amplified gene sequence comprises an amplicon containing 8q24.13 sequences, Smith (Table 7) teaches that the sequences of 8q24 are amplified in ovarian cancer and that the sequences of 8q24-25 are amplified in small colon carcinoma. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Smith so as to have used cells containing amplified sequences of 8q24 in order to haw identified anti-neoplastic agents useful for treating ovarian cancer or to have used cells containing amplified 8q24-25 sequences in order to have identified ant-neoplastic agents useful for treating small cell carcinomas. Thus, there is no special technical feature linking the recited groups, as would be necessary to fulfill the requirement for unity of invention.

Further, the claimed inventions do not share a linking technical feature because each of the claimed methods involve the use of different reagents, have different outcomes and different effects. As such, each of Groups I-XIII have a different objective and outcome and do not share the same corresponding technical feature.

Further restriction requirement applicable to invention I

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

the amplicons set forth in Table 2;

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable – i.e., a single amplicon or a particular combination of amplicons. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Claims 1-4 encompass the species of the distinct amplicons recited in Table 2.

The following claim(s) are generic: none.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The recited amplicons differ from one another with respect to their nucleotide structure, their

chromosomal location, the proteins that they encode, the types of cancers in which they are amplified and with respect to their biological activity effect. The amplicons thereby have a different chemical structure and different biological activity. Thus, the claimed genes do not have both a "common property or activity" and a common structure as would be required to show that the inventions are "of a similar nature."

Further restriction requirement applicable to invention II-X

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

the nucleic acids of SEQ ID NO: 1-3049 and the polypeptides encoded by SEQ ID NO: 1-3049.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable – i.e., a single nucleic acid or a particular combination of nucleic acids or a single polypeptide or a particular combination of polypeptides. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Claims 5-60 encompass the species of SEQ ID NO: 1-3049 or the polypeptide encoded by SEQ ID NO: 1-3049.

The following claim(s) are generic: none.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The recited nucleic acids differ from one another with respect to their nucleotide sequence, their location in the human genome, the cancers in which they are amplified and the proteins that they encode. The nucleic acids of SEQ ID NO: 1-3049 thereby have a different chemical structure and different biological activity. Similarly, the polypeptides encoded by SEQ ID NO: 1-3049 comprise distinct amino acid sequences, having different binding specificities and have different biological activities. Thus, the claimed nucleic acids and proteins do not have both a "common property or activity" and a common structure as would be required to show that the inventions are "of a similar nature."

Further restriction requirement applicable to invention VI

5. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

the different biological activities recited in claims 14-33.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable – i.e., one particular or one particular combination of the biological activities recited in claims 14-22. Note that this election must be commensurate with the election of a particular polypeptide or combination of polypeptides, as set forth above for the claims of Group VI. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Claim 14-33 encompass the recited species of different protein biological activities.

The following claim(s) are generic: claims 12, 13 and 34-39.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the recited biological activities have a different mechanism and effect and are assayed using different methodologies. The activities are associated with different polypeptides having different structures and biological effects. Thus, the claimed biological activities do not

have both a common structure and a "common property or activity" as would be required to show that the inventions are "of a similar nature."

6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is 571-272-0747. The examiner can normally be reached on Monday-Thursday (6:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carla Myers/

Primary Examiner, Art Unit 1634